Appendix E-2
Washington State Certificate of Need Program
Task Force Report

Public Comments

(*Editor's Note: the following letters have been repaginated for display purposes)*

Cancer Treatment Centers of America

Winning the fight against cancer, every day.®

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October 2, 2006

To: The Washington Health Care Authority

From: Melanie Stewart, Government Affairs
Cancer Treatment Centers of America

Recommendations to the Certificate of Need Task Force by the Cancer Treatment Centers of America

Recommendation 1:

The Department of Health should identify strategies for meeting established statutory timelines for Certificate of Need applications.

Comment:
Meeting statutory guidelines would eliminate one of the major shortcomings of the Program.

Recommendation 2:

The Department of Health should identify strategies to ensure that all statutory criteria for reviewing Certificate of Need applications are fully applied. The Department may also recommend amendments to statutory criteria, if necessary, to reflect the state's current health care system.

Comment:
Current Program decisions are made in the absence of a coherent state health policy regarding construction of health care facilities. As a result, recent Program decisions have focused instead on applying the literal terms of Department certificate of need regulations, regardless of the effect on the desirable new projects. Many of the regulations are ambiguous and the Program has adopted inconsistent interpretations of key points. The Program's inconsistency and delay frustrates all attempts by providers to plan and execute facility construction in a reasonable and orderly manner.

The Program's chronic inconsistency is at least as much of an obstacle to orderly facility planning and development as its failure to apply all statutory criteria.

Recommendation 3:

The Legislature should consider establishing consistent basic reporting requirements for all services and facilities that are subject to Certificate of Need review so that information related to each type of application will be readily available and reliable.

Comment:
The absence of consistent data for various health facilities, creates difficulties in measuring need and facility impact. Improvements in data availability and consistency would be beneficial.

The audit overlooks a greater problem in achieving an orderly process for determining need for new facilities and expansions. The Program lacks the expertise necessary to both understand the information it obtains and also use it in a meaningful way. As a result, the Program frequently reaches erroneous outcomes by misinterpreting and misapplying data. The Program should have greater access to expert resources needed to evaluate facility applications in the highly complex health care environment.

Recommendation 4:

In order to ensure ongoing consistency in both the analysis and final decisions for Certificate of Need applications, the Department of Health should electronically track program staff's application reviews and issued decisions, including the methods used in reviewing applications and the reasons for the final decisions. The Department of Health can then use this information to perform regular and ongoing reviews of decisions.

Comment:
Cancer Treatment Centers of America supports any efforts to increase consistency and accuracy in Program decision-making, including regular Department reviews. Quality control for final decisions has been a chronic problem and additional review could improve the quality and accuracy of final decisions.

Recommendation 5:

In accordance with statute, the Department of Health should revise its monitoring practices to include completed projects, as appropriate, in order to ensure applicants' compliance with issued Certificates of Need.

Comment:
Noncompliance with conditional Certificates of Need has not been a significant problem.

Recommendation 6:

The Department of Health should better use its website about the Certificate of Need program to make more information and their applications available to the public. This information should include: (1) the application forms; (2) status reports on the program's activities; and (3) performance data for the program.

Comment:
The Program recently has upgraded its website, making it more useful. In order to promote consistency of approach, it should make available on the website all decisions for at least the last five years. The decisions otherwise are available only upon request from the Program.

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October 2, 2006

Dear Certificate of Need Task Force:

DaVita, Inc. wishes to state for the record its observations and experiences with the state's CN program. We hope that these deficiencies in the program's operation will be reduced or eliminated by the Task Force's work. State government, providers and the public should work together to create a level playing field for providers seeking CN approvals for new and expanded kidney dialysis capacity so desperately needed by residents of Washington State.

Some facts about who we are may be in order. DaVita is a kidney dialysis provider serving over 870 patients with End Stage Renal Disease in 11 facilities in Washington State. We employ more than 200 caregivers. In order to stay alive, these patients require dialysis three times per week for 4 to 5 hours each treatment. DaVita is proud of the fact that our key patient outcomes are second to none in the nation. DaVita has received awards for "Leadership in Innovation," for being an "Exemplary Employer of Older Workers": and for best employer of workers over age 50. Kent Thiry, our CEO, is a frequent speaker on creating a value-based culture. Attached are a document describing the charitable activities DaVita initiated and supports and a second page about the company's story.

The CN application and appeals process has been a problem for many health care providers. Many applicants believe it is not a transparent and predictable process. Rather than facilitating and guiding facility planning, the CN process frustrates efforts at planning with ever-changing standards and interpretations, leading to unpredictable outcomes. With patients relying on us for access to high quality dialysis care, we request your assistance in improving the CN process.

We have an ongoing issue that serves as an excellent example of CN process problems. DaVita successfully applied in August 2003 for a CN to build a needed 16-station kidney dialysis facility in Tacoma. The Department of Health granted DaVita a CN but the decision was appealed by a competitor. Following reconsideration to correct a Department error, the Department withdrew the CN in September 2005.

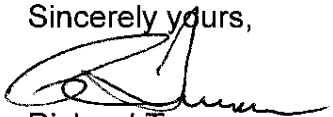
In the meantime, DaVita had completed the facility and prepared to open. Without the CN, it cannot lawfully open. This is a state of the art facility that now sits dark and unused in Tacoma when it could be used to treat underserved patients with severe illnesses. The closure has had a harsh impact on dialysis patients in the area, forcing them to travel to farther away facilities for treatment and robbing them of free time with their families and friends.

The Department refused to consider DaVita's reconsideration request. Recently, at the long-awaited hearing on DaVita's appeal, the Program announced that it had made another mistake in its decision and asserted a completely new basis for withdrawing DaVita's CN. DaVita was forced to request a halt to the hearing and an order from the Health Law Judge requiring the Department to again correct and clarify the grounds for its decision. The CN Program now has proposed an entirely new decision relying on grounds that DaVita believes are so profoundly flawed and depart so far from established Program practice as to raise serious issues of fundamental fairness.

Our efforts to highlight problems with the CON process have focused on our experience with our Tacoma application because it so clearly demonstrates that the process is broken. Despite finding need for new stations in the area, the CN Program has rejected on technical grounds two additional DaVita applications to expand facilities or build new facilities to meet the demand. Under such circumstances, extending the program's reach to include additional health care services represents questionable public policy.

DaVita intends to continue to help meet the dialysis needs of the people of Washington State by pursuing a strategy to expand where patient demand warrants it. With the Task Force's leadership, we hope that the CON process can become more consistent, predictable, timely and fair in meeting the dialysis needs of Washington residents now and in the future.

Sincerely yours,



Richard Turner
Division Vice President

Franciscan Health System

August 7, 2006

Cindy Watts, Ph.D.
Chair, Certificate of Need Task Force
Professor, University of Washington
P.O. Box 357660
Seattle, WA 98195

Dear Madam Chair:

Franciscan Health System is an integrated health care organization that includes St. Joseph Medical Center in Tacoma; St. Clare Hospital in Lakewood; St. Francis Hospital in Federal Way and soon, St. Anthony Hospital in Gig Harbor. It also includes some 33 Franciscan Medical Group primary-care and specialty-care clinics throughout Pierce, South King and South Kitsap counties; and Franciscan Hospice House in University Place. The mission of our not-for-profit, faith-based organization is to nurture the healing ministry of the Church, emphasize human dignity and social justice, and create healthier communities. In the twelve month period ending July 2005, we provided approximately $64 million in community benefit.

Franciscan has followed with great interest the proceedings of both the Certificate of Need Task Force (Task Force) and the Technical Advisory Committee (TAC). We are on record as supporting a strong, consistently administered and policy-based Certificate of Need program. We are also supporters of the language contained in Section 1 (4) of E2SHB 1688 which states that "the Certificate of Need statute plays a vital role and should be reexamined and strengthened to reflect changes in health care delivery and financing since its enactment." To that end, we are taking this opportunity to comment on the current state of affairs related to the regulation of ambulatory surgery centers (ASCs), and offer what we believe to be necessary changes so ambulatory surgery services in Washington are delivered in a manner consistent with the intent of RCW 70.38.

As you may be aware, ASCs are not licensed in the State of Washington. Additionally, if an ASC is owned by a "group practice" and the use of the ASC is not extended to physicians outside of the group practice, it is not subject to prior Certificate of Need review. The result has been a system where nearly any entity that so chooses can operate an ASC without Certificate of Need review.

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This has led to situations where:

1. "Niche" providers increasingly skim the marketplace, leaving less profitable cases and lower volumes for hospitals; and
2. Non-regulated ASCs can be developed in markets where there may be no community need, i.e., there is already an adequate supply of outpatient surgery providers—this also hurts regulated providers by increasing the supply of outpatient surgical facilities and thereby reducing their volumes. Further, given the lack of licensing, consumers do not have adequate information to make informed decisions about quality and outcomes.

When Certificate of Need review is required for an ASC that will be open to all licensed physicians, the Certificate of Need Program's (the Program) interpretation of the methodology contained in WAC is fundamentally flawed, due to use of both flawed underlying assumptions and outdated, incorrect utilization statistics. Thus, it is not surprising many of the Department's decisions are problematic. Finally, given that the Program currently does not monitor the charity care requirements it places on ASCs, we are also concerned that many ASCs are not doing their "fair share" under statute.

We are hopeful that the Task Force will make specific recommendations about how to strengthen the Certificate of Need Program's review and monitoring of ASCs. To facilitate your efforts, we have elaborated below on the current problems, and where applicable, have suggested necessary modifications:

1. Licensing: All ASCs not operated as part of another licensed health care facility (i.e.: a hospital) should be licensed. Minimum standards related to physical plant, operations and quality should be adopted.

2. Exemptions for "group practices" should either be eliminated, or the Program should adopt a formal definition of "group practice": The Program, to date, has been unwilling and/or unable to define what a "group practice" is for purposes of RCW 70.38 WAC 246-310. The lack of a clear definition has resulted in increasingly "creative" models proposed by those organizations intent on establishing ASCs but avoiding Certificate of Need; many such creative definitions are, in fact ultimately approved by the Department of Health.

In summary, there is no clear, consistent definition of group practice. Existing providers cannot rely on a consistent definition being applied. It is our experience that the Program has exempted many ASCs wherein no legitimate group practice can be discerned. We suggest that the Program either use the definition of a group practice as set forth in the Stark Law (see 42 CFR 411.352) or remove the exemption allowance altogether and require that all ASCs be subject to review.

3. Methodology for projecting need: The methodology in rule (WAC 246-310-270) is outdated, lacks an empirical basis and is poorly applied. It was originally developed in the early 1980s, at the time when the State Health Coordinating Council was actively promoting the development of freestanding surgical settings. Literal reading of current rule indicates that preference should be given to ASCs over hospital-based capacity only if, and when, the methodology determines that hospital or mixed use capacity is insufficient in a defined planning area. This makes little sense in settings where inpatient-only operating rooms are being counted as part of overall supply when they have dedicated uses. There should be distinction in the methodology on the demand and the supply side between inpatient and outpatient uses.

Regarding surgical utilization parameters used to calculate surgery volumes, e.g., minutes per surgery, or number of surgery minutes per operating room per year, WAC standards are well out of date. There needs to be a survey data base used, based on relatively complete, current provider practices. Further, there is no consistent data set the department employs to estimate a use rate, a key statistic for calculating estimated volume of surgeries for a study area. This, too, needs to be survey-based, driven off actual, current surgical volumes in a given area. Instead, review of recent department decisions indicates there are wide ranges of use rates allowed. We believe this makes no sense and that the figures should be data-driven and based on real statistics relevant to the study area.

There is also consistent, and frankly illogical misinterpretation of the methodology currently in practice by the Program. Specifically, when estimating future need (demand), the Program interprets the methodology as requiring it to ***include*** the volume/activity associated with all providers (exempt or non-exempt) in its estimation of a use rate. However, on the other hand, when counting the supply of operating rooms available to meet demand, the Department ***excludes*** the operating rooms located in exempt facilities from its count of available supply. With such an interpretation, absurd results are routinely generated—the Department consistently undercounts supply by ignoring exempt providers and approves applications it should not. In many communities that Franciscan is familiar with, up to 50% of all operating room capacity is currently located in these exempt facilities. The rationale that the Program has put forth to explain its policy of excluding operating rooms located in exempt facilities from its count of "supply" is that these exempt facilities do not meet the definition of an ASC found in WAC 246-310-010. We recommend that both the methodology and the definition in rule be revised.

4. Ongoing Monitoring: Charity care is an obligation that must be shared amongst providers. While the Program is increasingly placing charity care "conditions" on ASCs, it is not monitoring ongoing conformance. Anecdotally, we hear of many instances wherein underinsured or non-insured patients are being turned away from freestanding ASCs. The Program must assume responsibility for ongoing monitoring of all ASC's and have the ability to withdraw a Certificate of Need for noncompliance.

We both value and appreciate the work of the Task Force. I am available to answer any questions you may have. Thank you for your attention to this very serious matter.

Sincerely,

Laure C. Nichols

Laure Caillouette Nichols
Senior Vice President
Strategic Planning and Business Development

c. Certificate of Need Task Force
Robb Menual
Laurie Jinkins

Home Care Association of Washington

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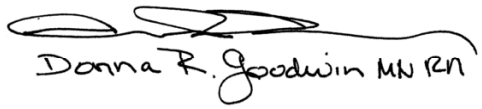
MEMO

To: Carolyn "Cindy" Watts, PhD, Chair, Certificate of Need Task Force
Representative Eileen Cody, RN, Task Force Member
Linda Glaeser, Lead Task Force Staff

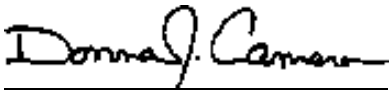
From: Donna Goodwin, RN, Vice President, Family Home Care, TAC Member
Donna Cameron, CAE, Executive Director, Home Care Association of Washington

Re: CN comments (in conjunction with the Washington State Hospice and Palliative Care Organization)

Date: October 6, 2006



Donna Goodwin, MN RN



Donna Cameron, CAE

Thank you for the opportunity to submit this Memo as a replacement for Memos sent on May 23rd and June 6th. At the time those Memos were written we did not completely understand Representative Cody's question concerning the home health and hospice marketplace as it relates to certificate of need (CN). While we understood that Representative Cody was asking if CN should apply to all portions of the marketplace, we did not understand that she envisioned two separate CN routes: one for agencies that wanted to access Medicare reimbursement, primarily, and one for agencies that wanted no access to Medicare reimbursement.

Summary: In response to Representative Cody's question, as we now understand it, we do not recommend requiring CN for home health or hospice agencies that do not want access to the Medicare marketplace. The following contains our rationale, as well as background information.

- Medicare is the key reimbursement source for home health services. In a survey of our members, respondents indicated that 76% of their revenue came from Medicare; 17% from Medicaid; 6% private insurance; and 1% private pay.
- The Medicare benefit for home health care has rigorous coverage criteria that must be met in order for a beneficiary to receive care. The Medicare benefit is restrictive and does not cover long-term chronic care needs, such as custodial or maintenance care. Non-Medicare services fill that gap.
- Of the 93 state licensed home health agencies, 61 are Medicare certified. Of the remaining 32 state licensed only agencies, 8 are affiliated with Medicare certified agencies.
- The non-Medicare home health marketplace has certain constraints that make it very unlikely that it would produce demand for these services, unrelated to need.

    - The only way a non-Medicare certified agency can receive reimbursement for traditional Medicare services is if there is no Medicare-certified agency that can provide them in a given service area. This happens infrequently.
    - Non-Medicare certified agencies have far less access to third party reimbursement than Medicare certified agencies. In a survey of our membership, over 75% said that third party payers required Medicare certification or JCAHO accreditation.
    - Non-Medicare-certified agencies rely heavily on private pay, or persons paying without regard to any insurance. This portion of the market is particularly susceptible to traditional economic principles of supply and demand because consumers are paying out of pocket.
    - Some non-Medicare certified home health agencies provide services through contracts with DSHS' Aging and Adult Services Division. But, we believe this number is relatively low because the reimbursements are below cost.
- Non-Medicare home health services are based on a different delivery model than Medicare home health services. Medicare home health is a " per visit" and "intermittent" or "part-time" service which means that skilled health care professionals (nurses, PT's, OT's, home health aides, etc) provide a service during an appointment period that could last from 15 minutes to over an hour. As noted above, Medicare services are not all inclusive and do not cover custodial or health maintenance services.
- Non-Medicare home health services are "hourly" meaning that health care professionals are in the home providing care on a more continuous or "hourly" basis, as determined by the consumer's needs and their ability to pay.
- The majority of Medicare agencies are not interested in providing "hourly" care. As noted above, it is a completely different model of care. And for those that are interested, they often obtain a separate home health license.
- Medicare agencies rely on the existence of non-Medicare agencies to fill in the gap for people by providing these additional services that often make the difference in a person being able to remain in their own home.
- State licensed only, or non-Medicare certified home health agencies, are not a competitive threat to Medicare certified home health agencies because their "business" is so completely different.
- For hospice agencies, there is essentially only one marketplace. Virtually all state licensed hospice agencies are also Medicare certified. For hospice, services are either covered under Medicare or private insurance, or it ends up as charity care. Hospice is a comprehensive service.

The following comments provide some additional detail.

1. The Department of Health (DOH) licenses in-home services agencies according to the following categories when specific regulatory requirements are met under Chapter 70.127 RCW: home health, hospice, home, care, and hospice care centers. Because there is the most confusion between home health and home care agencies, we are providing some additional detail.
2. Home health agencies are required to be licensed by the Department of Health (DOH) under Chapter 70.127 RCW. Home health agencies are defined as "a person administering or providing *two or more* home health services…to individuals in places of temporary or permanent residence." Home health services include nursing, home health aide, physical, occupational, speech and respiratory therapies, nutritional services, medical social services and home medical supplies or equipment. Persons that provide a *single* service may *elect* to become licensed, but are not required to be licensed.

3. Home health agencies that want to access Medicare reimbursement must be state licensed, Medicare certified, and have a certificate of need for their service area. A service area is at least one county, but can be more than one county. The Department of Health is the surveyor for Medicare certification.
4. Home care agencies are required to be licensed by the Department of Health. Home care agencies provide *nonmedical* services and assistance to include personal care such as assistance with dressing, feeding, and personal hygiene to facilitate self-care; homemaker assistance with household tasks, such as housekeeping, shopping, meal planning and preparation, and transportation; respite care assistance and support provided to the family; or other nonmedical services or delegated tasks of nursing.
5. Home care agencies have *never* been subject to certificate of need. We are not recommending that this be changed. The primary source of reimbursement for home care agencies is through DSHS' Aging and Disability Services Administration (ADSA). While the number of applicants for home care agency licensure has been increasing, a significant number of these applicants, once granted licensure, have no or very few clients. That's because in order to access ADSA programs and their clients, AAA's require agencies to have a certain number of years experience in providing services. This requirement essentially limits the number of the newer providers that deliver services, unless they can find a niche in the private pay marketplace.

Based on this information and analysis, we do not recommend any change to the scope of the certificate of program for home health, hospice, or home care agencies. We do not recommend requiring certificate of need for home health or hospice agencies that do not want access to the Medicare marketplace. We do believe certificate of need should be retained for those home health and hospice agencies that want access to Medicare. Please see our April 2006 Memo to Chair Watts for more details.

cc: Anne Koepsell, WSHPCO
Gail McGaffick, JD

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October 2, 2006

CON Task Force

Proliance Surgeons, Inc., P.S. is an interested party in the CON Task Force and the outcomes from the process.

Proliance Surgeons has applied for and received 3 Certificates of Need, as well as several "Exemptions" from a Certificate of Need from the Department of Health. This experience with the process is the basis for several of these comments.

For background, Proliance Surgeons, Inc., P.S. is a "for-profit" personal service corporation of physicians with offices in Western Washington from Tacoma to Anacortes. The corporation, besides being a physician office based practice, includes several ambulatory surgery centers, imaging (MRI) centers and physical/occupational therapy offices. The group is comprised of approximately 130 physicians/surgeons and 80 ancillary providers. The group was formed in 1993 and changed its name to Proliance Surgeons in 2002. Our surgeons perform surgery at the majority of the hospitals in the area, as well as our ambulatory surgery centers. While Proliance Surgeons is a "for-profit" corporation, our charitable care is at levels comparable to all the "non-profit" hospitals in our service area.

We do not agree with an expansion of the Certificate of Need program and strongly recommend repealing the program. Certificate of Need is not a proven cost saving program. A comparison of States that have and do not have a Certificate of Need program do not show a difference in the cost of services. We recommend appropriate and proven cost saving measures, not a tried and failed method.

Some of the frustrations with the program:

- Delays
- No requirement for DOH to follow through with deadlines
- Interpretation of rules, not following RCW
- Inflexibility of program
- Rules not applied uniformly
- Timelines not applied uniformly

I hope that this helps as you look at the Certificate of Need process and gives you guidance in abolishing rather than expanding the program. Thank you for allowing us to provide this information.

David G. Fitzgerald
CEO